

T-STAT - erythromycin solution
Bristol-Myers Squibb Company

For topical use only. Not for ophthalmic use.

DESCRIPTION

Erythromycin is an antibiotic produced from a strain of *Streptomyces erythraeus*. It is basic and readily forms salts with acids. Each ml of T-STAT (erythromycin) 2.0% Topical Solution contains 20 mg of erythromycin base in a vehicle consisting of alcohol (71.2%), propylene glycol and fragrance. It may contain citric acid to adjust pH.

ACTIONS

Although the mechanism by which T-STAT Solution acts in reducing inflammatory lesions of acne vulgaris is unknown, it is presumably due to its antibiotic action.

INDICATIONS

T-STAT Solution is indicated for the topical control of acne vulgaris.

CONTRAINDICATIONS

T-STAT Solution is contraindicated in persons who have shown hypersensitivity to any of its ingredients.

WARNING

The safe use of T-STAT (erythromycin) 2.0% Solution during pregnancy or lactation has not been established.

PRECAUTIONS

General

The use of antibiotic agents may be associated with the overgrowth of antibiotic-resistant organisms. If this occurs, administration of this drug should be discontinued and appropriate measures taken.

Information for Patients

T-STAT Solution is for external use only and should be kept away from the eyes, nose, mouth, and other mucous membranes. Concomitant topical acne therapy should be used with caution because a cumulative irritant effect may occur, especially with the use of peeling, desquamating, or abrasive agents.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term animal studies to evaluate carcinogenic potential, mutagenicity, or the effect on fertility of erythromycin have not been performed.

Pregnancy: Pregnancy Category C

Animal reproduction studies have not been conducted with erythromycin. It is also not known whether erythromycin can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Erythromycin should be given to a pregnant woman only if clearly needed.

Nursing Mothers

Erythromycin is excreted in breast milk. Caution should be exercised when erythromycin is administered to a nursing woman.

ADVERSE REACTIONS

Adverse conditions reported include dryness, tenderness, pruritis, desquamation, erythema, oiliness, and burning sensation. Irritation of the eyes has also been reported. A case of generalized urticarial reaction, possibly related to the drug, which required the use of systemic steroid therapy has been reported.

DOSAGE AND ADMINISTRATION

T-STAT Solution or Pads should be applied over the affected area twice a day after the skin is thoroughly washed with warm water and soap and patted dry. Acne lesions on the face, neck, shoulder, chest, and back may be treated in this manner. Additional pads may be used, if needed.

This medication should be applied with applicator top or the disposable applicator pads. If fingertips or pads are used, wash hands after application. Drying and peeling may be controlled by reducing the frequency of applications.

HOW SUPPLIED

T-STAT Solution, 60 ml plastic bottle with optional applicator, NDC 0072-8300-60. T-STAT Pads, 60 disposable premoistened applicator pads in a plastic jar. NDC 0072-8303-60. Store in a dry place at temperatures between 15°C and 25°C (59°F and 77°F).

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